UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,093	06/15/2006	Andreas Nandy	MERCK-3179	1555

23599 7590 09/21/2009

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
ROONEY, NORA MAUREEN	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
09/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/583,093	NANDY ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *10-12,18 and 19*.
   Claim(s) withdrawn from consideration: *1-9 and 14-17*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Maher M. Haddad/
Primary Examiner, Art Unit 1644

Continuation of 3. NOTE: The polypeptides of SEQ ID NO:2 and SEQ ID NO:4 have not been searched. As such, a search must be performed and the claims will require further consideration.

Continuation of 5. Applicant's reply has overcome the following rejection(s): No rejections have been overcome by Applicant's response filed on 09/04/2009.

First, the rejections of claims 10-12 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,759,234, Bose et al., Zhou et al. and WO 96/07428 stand for the same reasons as set forth in the Office Action mailed on 09/30/2008.

As an intial matter, Applicant has included part of a search report on a sequence search submitted in the Application. First, the sequence search results are not published or public, so the Examiner would like to call attention to Applicant that by including this information in their response they are making that information of public record.

As set forth in the Office Action mailed on 06/09/2009, the recitation of being encoded by SEQ ID NO:1 or SEQ ID NO:3 is inherent in the Lol p IV polypeptide. Since the office does not have a laboratory to test the reference Lol p IV protein, it is applicant's burden to show that the reference Lol p IV protein is not encoded by SEQ ID NO:I or SEQ ID NO:3 as recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980). The disclosure of a polypeptide encoded by SEQ ID NO: 1 or 3 is only further characterization of otherwise old product. The mere sequencing of a product, by itself, does not render the product novel. Applicant's citation to the sequence search results and submission of Exhibit A is not sufficient to prove that the reference Lol p IV protein is not encoded by SEQ ID NO:1 or SEQ ID NO:3. Furthermore, the references are not required to provide polypeptide sequences to anticipate the instant claims, contrary to Applicant's assertion. As such the rejections are maintained.

Applicant's argument with regard to 112, first paragraph enablement is unpersuasive as well. Applicant argues that the specification provides guidance regarding the specific epitopes in allergens and how such could be manipulated for reliable hyposensitisation and that allergen-encoding DNA vaccines provide allergen-specific immune responses. In general, Applicant argues, that the specification discloses strategies to minimize the risks of side effects with the development of T-cell reactive fragments with reduced or no IgE-reactivity leading to hypoallergenic peptides (see, page 8, lines 15-26). This argument is entirely unpersuasive. First, DNA vaccines have no relevance to the instant rejection. The claims are directed to polypeptides and medicaments thereof. The claims are in no way directed to DNA vaccination. Second, the claims are also not directed to T cell epitopes or fragments or hypoallergenic variants. The claims are specifically directed to compositions comprising polypeptides encoded by SEQ ID NO:1 or SEQ ID NO:3. Therefore, whether variants or fragments may be used in a medicament bears no relevance to the instant claim rejection. The claims are being rejected based on the Examiner's contention that whole allergen immunotherapy is unpredicatble and often dangerous in vivo. The claims are specifically directed to compositions comprising whole allergens for use in immunotherapy. Therefore, the Examiner's argument and the evidence of Tarzi is not weak nor is it unpersuasive. Applicant is required to show that the compositions being claimed can actually work as a medicament as is being claimed. The teaching of Tarzi et al. is sufficient to show that whole allergen immunotherapy is unpredictable and that all allergens cannot be effectively used in vivo. It is now up to Applicant to prove that, contrary to Tarzi's teachings, this Lol p IV whole allergen may be used in vivo to treat allergic disease. Therefore, for reasons of record, the rejection is maintained.

Applicant has not responded to the rejection under 35 U.S.C. 101. Therefore, the rejection stands for reasons of record.